UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

UNIVERSITY OF UTAH,

Plaintiff

V.

Civil Action

No. 11-10484-PBS

MAX-PLANCK-GESELLSCHAFT ZUR

FÖERDERUNG DER WISSENSCHAFTEN

e.V., et al.,

Defendants

)

Defendants

MEMORANDUM AND ORDER

September 28, 2015

Saris, C.J.

INTRODUCTION

This case concerns the field of RNA interference (RNAi), which is a process for inhibiting gene expression also known as "gene silencing." RNAi plays an important role in defending cells against viruses and other diseases. In 2011, plaintiff University of Utah (UUtah) brought this action against Max-Planck-Gesellschaft Zur Föerderung Der Wissenschaften e.V. (Max Planck), the Whitehead Institute for Biomedical Research (Whitehead), the Massachusetts Institute of Technology (MIT),

¹ <u>See generally Max-Planck-Gesellschaft Zur Föerderung Der Wissenschaften e.V. v. Whitehead Inst. for Biomed. Research, 650 F. Supp. 2d 114, 116 (D. Mass. 2009) (summarizing scientific background).</u>

Alnylam Pharmaceuticals, Inc. (Alnylam), and others, seeking correction of inventorship under 35 U.S.C. § 256 (Docket No. 8). The key contention is that a UUtah faculty member, Dr. Brenda Bass, should be named a joint inventor of a family of patents known as the "Tuschl II Patents." The defendants moved for summary judgment (Docket No. 165). After hearing, the motion is ALLOWED.²

FACTUAL BACKGROUND

The following facts are undisputed except where stated.

I. Science of RNA Interference

A brief tutorial explaining RNA interference is helpful in understanding the inventorship dispute. The human genome is comprised of approximately 22,000 genes, each embodied as a region of deoxyribonucleic acid (DNA) that contains codes for the synthesis of certain proteins. DNA, which consists of building blocks known as "nucleotides," occurs in the familiar "double helix" shape, with two strands coiled around the same

² UUtah further alleged unjust enrichment, common law unfair

both parties agreed at the hearing, there is no basis for UUtah's state law claims if Bass is not a joint inventor; I therefore ALLOW the motion for summary judgment on that issue. Furthermore, since neither Putnam's nor Kunin's testimony influenced my analysis here, I DENY the cross-motions as moot.

competition, false advertising, and violations of M.G.L. c. 93A, and Max Planck filed a motion for summary judgment regarding these claims as well (Docket No. 168). The parties also filed cross-motions to exclude certain expert testimony from Dr. Jonathan Putnam and Dr. Stephen Kunin (Docket Nos. 205, 209). As

axis. One end of a chain of DNA is known as the three prime (3') end, while the other is called the five prime (5') end.

The process by which a cell makes a protein involves two steps, transcription and translation. When a gene coding for a particular protein becomes active within a cell, the two strands of DNA for that gene unwind. During transcription, the cell reads the code in one DNA strand and produces a single-stranded chain of ribonucleic acid (RNA) called messenger RNA (mRNA), which contains the code to produce the protein. During translation, the cell reads the code in the mRNA strand and produces the protein.

During RNAi, a form of double-stranded RNA (dsRNA) is introduced into a cell. Since RNA is typically single-stranded, this double-stranded form triggers the destruction of the dsRNA and any mRNA having a substantially similar genetic code. Once an mRNA strand is destroyed, it cannot be translated into a protein. This effectively "silences" the gene that codes for that protein and prevents it from promoting disease. The process of gene silencing has potential therapeutic value because it provides a defense against viral infections and other diseases.

II. The Tuschl I and Tuschl II Patents

The Tuschl I patents, filed by inventors Thomas Tuschl, Philip Sharp, David Bartel, and Philip Zamore in March 2000, involved the discovery of the molecular mechanism underlying

RNAi in a *Drosophila* lysate (a composition of fruit fly embryos whose cell walls have broken down).

The inventors learned that long dsRNA introduced into the Drosophila lysate were cleaved into short dsRNA fragments. Specifically, the inventors found, most of the cleavage sites occurred at intervals of 21-23 nucleotides, and short dsRNAs of this specific length that were isolated from the Drosophila lysate caused RNAi. These findings appeared in an article in the prestigious scientific journal Cell on March 31, 2000, titled "RNAi: Double-Stranded RNA Directs the ATP-Dependent Cleavage of mRNA at 21 to 23 Nucleotide Intervals." Docket No. 182, Boebel Decl., Ex. 67. The article does not discuss the presence of 3' overhangs on short dsRNAs, or RNase III family enzymes as they relate to the generation of short dsRNAs.

The Tuschl II patents, filed by Tuschl, Sayda Elbashir, and Winifried Lendeckel in December 2000, claim a molecule with short dsRNA fragments known as short-interfering RNA (siRNA).

Claim One of U.S. Patent No. 8,372,968 reads:

An isolated double-stranded RNA molecule, which is a non-enzymatically cleaved RNA molecule, wherein:

- (i) each RNA strand independently consists of 19-23 nucleotides in length, and
- (ii) at least one strand has a single-stranded 3'-overhang from 1 to 3 nucleotides,

wherein said double-stranded RNA molecule is capable of target-specific RNA interference.

Docket No. 172, Haberny Aff., Ex. 14, Column 65-66, No. 1. The underlined portion has particular significance for purposes of the present inventorship dispute. The Tuschl II patents also claim methods of preparing siRNAs with 3' overhangs ranging from 1-5 nucleotides. One such claim reads:

A method for preparing a double stranded RNA molecule which mediates the cleavage of an mRNA in a mammalian cell, comprising

- (a) synthesizing two RNA strands each having a length from 19-25 nucleotides, and
- (b) combining the synthesized RNA strands under conditions suitable to form a double stranded RNA molecule, wherein said double stranded RNA molecule has a double stranded region of 14-24 nucleotides in length and one or two 3'overhang regions of 1-5 nucleotides in length.

Haberny Aff., Ex. 11 at Column 65-66, No. 1. One key difference between the Tuschl I and Tuschl II patents is that the Tuschl II patents claim RNA molecules with 3' overhangs that can cause RNAi in mammalian cells. See Max-Planck-Gesellschaft, 650 F. Supp. 2d at 117-18. As discussed below, a description of the inventions in the Tuschl II patents was ultimately published in an article titled "RNA interference is mediated by 21- and 22-nucleotide RNAs."

III. Dr. Bass's Minireview

On April 28, 2000, Dr. Brenda Bass, a tenured professor at UUtah, published a minireview in *Cell* magazine. *Cell* asked Bass

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³ Bass received her bachelor's degree from Colorado College at Colorado Springs, and her Ph.D. from the University of Colorado,

to review the Tuschl I article published on March 31, 2000, as well as several others, and to summarize the state of RNAi research. Bass's minireview included a prediction about how a natural enzymatic cellular process might cleave long dsRNA into the shorter dsRNA fragments described in the Tuschl I article. Specifically, Bass proposed that a certain enzyme in the RNase III family - known by the scientific community as "Dicer" - might cleave long dsRNA into siRNA. She also stated that the resulting siRNA fragments might contain one or two singlestranded nucleotides that extend beyond the double-stranded portion of the fragment at the 3' end of the molecule, but that these 3' overhangs would ultimately be "trimmed" to 21 and 22 nucleotide pieces. Bass stated,

If RNAi involves an RNase III-like enzyme, it might explain why the small RNAs observed by Zamore and Tuschl range from 21-23 nucleotides. The initial cleavage might produce dsRNAs comprised of sense and antisense 23-mers, but the 3' overhangs would be more accessible to single-strand-specific nucleases present in the extract, and trimmed to 21 and 22 nucleotide pieces.

Haberny Aff., Ex. 1 at 4.

As a courtesy, *Cell* sent Tuschl a draft of the minireview on April 5, 2000, twenty-three days before its publication. This draft addressed the Tuschl I article and contained the same

Boulder. After completing a postdoctoral position at the Fred Hutchinson Cancer Center in Seattle, she was hired by UUtah into a tenure track professorship. Bass is currently a Distinguished Professor of Biochemistry Research at that university.

prediction, discussed above, that eventually appeared in the published piece. *Cell* also asked Dr. Zamore, a co-inventor of the Tuschl I patents, to submit comments on the draft minireview before it went to press. Tuschl wrote an email to Zamore the day he received the preprint:

dear phil, i very much like brenda bass's review. . . I was not well informed on the typical product length generated by RNase III degradation[.] that our 21-23mers carry most likely a 5' phosphate (?) and a few 3' hydroxyl support this idea.

Boebel Decl., Ex. 20 at ¶ 96.

Prior to the minireview's publication, Tuschl drew a siRNA molecule with two-nucleotide 3' overhangs in the notebook of his co-inventor Dr. Lendeckel. The drawing was dated April 14, 2000, nine days after Tuschl received the preprint. Tuschl said of the drawing,

about the Brenda Bass review, there was the hypothesis that RNase III could be involved, and I think it's an illustration of possible structures that you might have to deal with when you look on RNA . . . to make sure that . . . possible structures in that mixture would be able to be identified with the method that we were trying to develop.

Boebel Decl., Ex. 40, Tuschl <u>Whitehead</u> Depo. Tr. at 277-79. On April 28, 2000, the minireview was published.

IV. The Scientific Conferences

Bass attended two conferences, one at the Banbury Center in Cold Spring Harbor, New York in April, 2000 and the other in Uppsala, Sweden in August, 2000. At Banbury, Bass gave a slideshow presentation on the same material contained in her

minireview. Her slideshow included a note reading, "dsRNA cleavage products are ~ 23 nucleotides (nt) long, w/ 3' overhangs of t nt. (like RNase III products)." Boebel Decl., Ex. 20 at ¶ 90. Although Zamore attended the Banbury Conference, Zamore and Bass had no substantive discussions, and the parties do not recall whether Zamore went to Bass's presentation.

Tuschl attended the Uppsala Conference. Over dinner, Bass told Tuschl that she had been successful in using dsRNA in a species of nematode worm, *C. elegans*, to "knock down RNAi components," meaning to destroy pieces of mRNA that code for specific proteins and thus prevent the expression of those proteins. Haberny Aff., Ex. 2, Bass Depo. at 126:14. Tuschl subsequently sent Zamore an email which referenced his interaction with Bass at Uppsala:

One word of caution with northern blots of 21mers. brenda bass, who was also at the meeting, was telling me that she gets the 21mer production to go in C. elegans extracts but that the 21mers come and go and that it appears to have to do with the type of membrane one is using.

Boebel Decl., Ex. 9.

Bass never interacted with Dr. Elbashir or Dr. Lendeckel, the other named Tuschl II inventors.

V. The Tuschl II Article

On October 25, 2000, Tuschl and his colleagues submitted a manuscript of the Tuschl II article to *Genes & Development* magazine. Titled "RNA is mediated by 21- and 22- nucleotide

RNAS," the article was published on January 15, 2001; it demonstrated that synthetic 21- and 22- nucleotide RNAs facilitate sequence-specific mRNA degradation "when base paired with 3' overhanging ends." Haberny Aff., Ex. 8 at 188. At the behest of Genes & Development, and unbeknownst to Tuschl, Bass served as an anonymous referee of the Tuschl II manuscript. She recommended the manuscript for publication, stating that the research of "Tuschl and collaborators substantially adds to our understanding of the mechanism of RNAi" and will be "extremely important for those directly involved in RNAi studies." Bass Depo. at 101:20-102:3.

On December 1, 2000 - two months after the named coinventors submitting the Tuschl II manuscript to Genes &

Development magazine - Max Planck filed European Patent

Application No. EP00126325.0 (the '325 Application). The Tuschl

II patents claim priority to the '325 Application and include

ten issued U.S. patents. The patents all name Tuschl, Elbashir,

and Lendeckel as inventors, and are co-assigned to Max Planck,

Whitehead, MIT, and UMass. Bass did not do any of the laboratory

experiments or generate any of the data included in the Tuschl

II patents. Bass's minireview was cited as prior art during the

prosecution of the Tuschl II patents before the United States

Patent and Trademark Office, and all the patents issued as novel

and non-obvious over the minireview. Eighteen separate patent offices have followed suit.

DISCUSSION

I. Summary Judgment Standard

Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1472 (Fed. Cir. 1997). The facts, and all reasonable inferences that may be drawn from them, must be viewed in the light most favorable to the non-moving party. Guzman-Rivera v. Rivera-Cruz, 29 F.3d 3, 4 (1st Cir. 1994). "The standard of proof on an issue must be considered when evaluating the sufficiency of the evidence on a motion for summary judgment."

Id. Therefore, the summary judgment record should be considered in light of the plaintiff's burden to show joint inventorship by clear and convincing evidence. See, e.g., Linear Tech. Corp. v.

Impala Linear Corp., 379 F.3d 1311, 1327 (Fed. Cir. 2004).

II. Correction of Inventorship

35 U.S.C. § 256 provides that whenever "through error an inventor is not named in an issued patent, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error." In turn, 35 U.S.C. § 116 establishes the standard for joint inventorship:

Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

In a § 256 proceeding, "the inventors as named in an issued patent are presumed to be correct." Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352, 1358 (Fed. Cir. 2004) (internal quotation omitted). Accordingly, the party alleging non-joinder of inventors must "meet the heavy burden of proving its case by clear and convincing evidence." Id. "The clear and convincing burden of proof is applied to joint inventorship disputes because of a 'strong temptation for persons who consulted with the inventor and provided him with materials and advice, to reconstruct, so as to further their own position, the extent of their contribution to the conception of the invention.'" Id. at 1366-67 (citation omitted).

A putative co-inventor's testimony cannot, standing alone, rise to the level of clear and convincing evidence. Ethicon,

Inc. v. United States Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998). To meet this burden, would-be co-inventors "must prove their contribution to the conception of the invention with more than their own testimony concerning the relevant facts."

Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n, 383 F.3d

1352, 1382 (Fed. Cir. 2004). Courts use a "rule of reason"

analysis to determine whether a putative co-inventor's testimony

has been sufficiently corroborated, which includes evaluation of contemporary records, oral testimony from someone other than the putative inventor, or other circumstantial evidence. <u>Id.</u> "The determination of whether a person is a joint inventor is fact-specific, and no bright-line standard will suffice in every case." <u>Fina Oil</u>, 123 F.3d at 1472. The overall inventorship determination, though, is a question of law, premised on underlying questions of fact. Eli Lilly, 376 F.3d at 1362.

One major requirement for establishing joint inventorship is collaboration. Joint inventorship may only arise "when collaboration or concerted effort occurs - that is, when the inventors have some open line of communication" surrounding their inventive efforts. Id. at 1359. Otherwise put, an individual must "demonstrate that his labors were conjoined with the efforts of the named inventors." Id. The resulting invention must be "the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts." Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co., 973 F.2d 911, 916 (Fed. Cir. 1992) (emphases in original). "Individuals cannot be joint inventors if they are completely ignorant of what each other has done until . . . after their individual independent efforts. They cannot be totally independent of each other and be joint inventors." Id. at 917. Moreover, "co-inventors must collaborate

and work together to collectively have a definite and permanent idea of the complete invention." <u>Vanderbilt Univ. v. ICOS Corp.</u>, 601 F.3d 1297, 1308 (Fed. Cir. 2010). In other words,

the statutory word "jointly" is not mere surplusage. For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting.

Kimberly-Clark, 973 F.2d at 917.

A party seeking to be named joint inventor must also prove, by clear and convincing evidence, that her contribution to the invention in question was significant. Section 116 "sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor." Fina Oil, 123 F.3d at 1473. However, each joint inventor must "make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." Id. "The line between actual contributions to conception and the remaining, more prosaic contributions to the inventive process that do not render the contributor a coinventor is sometimes a difficult one to draw." Eli Lilly, 376 F.3d at 1359. For example, a contribution to conception does not include assisting the actual inventor after conception of the claimed invention. Id.

III. Subject Matter of the Minireview

Plaintiff's core inventorship contention is that Bass conceived of the critical structural characteristic of short-interfering RNAs claimed in the Tuschl II patents — that siRNAs have overhangs of approximately 2 nucleotides on their 3' end. At the hearing, the defendants argued as a threshold matter that this conception, as presented in the minireview, was not patent eligible under 35 U.S.C. § 101 because Bass's thesis was merely an "unclaimed identification of a natural phenomenon." Docket No. 232, Hrg. Tr. at 15:3-4. This contention did not appear in the briefs.

In Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 133 S.Ct. 2107, 2116 (2013), the Supreme Court concluded that "[1]aws of nature, natural phenomena, and abstract ideas are not patentable," since to hold otherwise "would be at odds with the very point of patents, which exist to promote creation." Id. "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Id. at 2117. Instead, an inventor seeking patent protection must alter the natural phenomenon in some way. See id. at 2116 (plaintiff could not patent precise location and sequence of certain genes linked to breast cancer because "location and order of the nucleotides existed in nature before Myriad found them"). In the defendants' view, the same is true of Bass's discovery of the enzyme Dicer's

role in cleaving dsRNA into siRNA. Bass did not create anything, they argue, because the minireview simply identified a natural phenomenon. Indeed, the defendants point out that neither Bass nor UUtah ever sought patent protection for her Dicer research.

But Max Planck cites no case law that a putative joint inventor must make a contribution to conception that is itself independently patentable under § 101. She need only "contribute to the conception of the invention," Burroughs Wellcome Co. v.

Barr Labs., Inc., 40 F.3d 1223, 1227-28 (Fed. Cir. 1994), since it "is not necessary that the entire inventive concept should occur to each of the joint inventors." Kimberly-Clark, 973 F.2d at 916; See also Rothschild v. Cree, Inc., 711 F. Supp. 2d 173, 203 (D. Mass. 2010) (joint inventor's alleged contribution "should be assessed by asking whether the contribution helped to make the invention patentable"). However, even though Myriad is no bar to UUtah's joint inventorship claim, its claim suffers from a myriad of other deficiencies.

IV. Collaboration

The basic dispute is over collaboration. UUtah contends that Bass and Tuschl collaborated because Tuschl read the minireview and built upon it in his own work. The defendants respond that the Tuschl II inventors were free to use Bass's research once it entered the public domain via the minireview's publication in Cell magazine. In turn, UUtah concedes that the

Tuschl II inventors were entitled to use Bass's conception once published, but argues that "use of concepts in the public domain does not include their appropriation into a patent that removes them from the public domain." Docket No. 194, Pls. Surreply at 19. The defendants finally retort that UUtah is, in essence, raising an issue of invalidity, not one of co-inventorship. The defendants ultimately prevail.

Generally speaking, scientific articles become part of the prior art on the date of their publication. 2 Practitioner's Manual of Patent Examining Proc. § 2128.02 ("A journal article or other publication becomes available as prior art on the date . . . it is received by a member of the public."); Cytyc Corp. v. TriPath Imaging, Inc., 505 F. Supp. 2d 199, 227 (D. Mass. 2007) (technology not "documented in a published article nor publicly displayed before the effective filing date" of patent was not prior art). "Prior art refers to all published articles, known techniques, and marketed products." Robert P. Merges et al., Intellectual Property in the New Technology Age, 131 (2d ed. 2000); see also 35 U.S.C. § 102(a)(1) (party is entitled to seek patent protection unless claimed invention was "described in a printed publication . . . or otherwise available to the public before the effective filing date of the claimed invention"). It is well-settled that a "contribution of information in the prior art cannot give rise to joint

inventorship because it is not a contribution to conception."

Eli Lilly, 376 F.3d at 1362; see also Gen. Elec. Co. v. Wilkins,

750 F.3d 1324, 1331-32 (Fed. Cir. 2014) (rejecting joint
inventorship claim since "if all [putative inventor] allegedly

contributed to the . . . patent was the idea to use [certain
instrumentality], then he would have contributed nothing beyond
what was already known in the art").

Here, once the minireview went to press, Bass's Dicer research was "assimilated into the storehouse of knowledge that comprises ordinary skill in the art." Falana v. Kent State Univ., 669 F.3d 1349, 1358 (Fed. Cir. 2012). For this reason, even if Tuschl relied on Bass's published hypothesis in researching RNA and appropriated it into his patent claim, this appropriation of published prior art did not, without more, amount to collaboration. See, e.g., Sewall v. Walters, 21 F.3d 411, 416 (Fed. Cir. 1995) (no joint inventorship where named inventor built off of method already disclosed by would-be joint inventor in prior art patent); Eli Lilly, 376 F.2d at 1362 (no joint inventorship where putative inventor "contributed only a mere realization about the chemical properties of [a drug] that were in the public domain"). Consistent with this case law, Bass later testified it would not "ever have crossed [her] mind to say" that she was not being properly credited as the discoverer

of 3' overhangs in regard to the Tuschl II article. Bass Depo. at 102:19-25.

Accordingly, UUtah's argument boils down to an allegation that, during the three weeks between his receipt of the preprint and its publication, Tuschl used Bass's research, maintained an open line of communication with Bass, and structured his siRNA testing around her Dicer hypothesis. Specifically, UUtah argues that Tuschl refined his research path before the minireview went to press in order to ensure that his siRNA synthesis protocol would be compatible with Bass's proposal. The defendants dispute this version of events, arguing that Tuschl was familiar with numerous possible siRNA structures before reading the minireview.

When all reasonable inferences are drawn in favor of UUtah, the evidence supports UUtah's theory that Tuschl incorporated Bass's hypothesis regarding the 3' overhang into his research, that her prediction was a significant contribution to the ultimate patented invention, and that this contribution was corroborated by existing documentation - namely, the minireview itself. As Dr. Zamore put it, "everything we did concerning the structure of what we now call siRNAs was in the shadow of this prediction by Brenda [Bass]." Boebel Decl., Ex. 20, Jorgensen Report at ¶ 98. However, UUtah cannot ultimately show that Bass and Tuschl collaborated because there is no evidence that they

worked together, spoke together, or had preserved any open line of communication during the relevant three-week period. That Tuschl read Bass's minireview before it was published does not itself amount to collaboration.

In support of its position, UUtah points to Kimberly-Clark, which stated that "one inventor seeing a relevant report and building upon it" could be a factor in favor of joint inventorship. 973 F.2d at 917. In Kimberly-Clark, defendants Proctor & Gamble sought to show that three of its employees were joint inventors for purposes of establishing patent priority over a Kimberly-Clark patent. Id. at 915-16. Though working individually, all three employees sought to improve disposable diapers by adding leak-proof inner flaps. Id. at 912-13. The employees shared a common inventive goal and worked on precisely the same element of the product. Had one employee seen the report of another and built upon it, therefore, the pre-existing relationship between the employees and the unity of their research aims might have satisfied the quantum of collaboration for joint inventorship.

But the court in Kimberly-Clark found otherwise, since no such report existed and the putative inventors were "completely ignorant" of the named inventor's work. Id.; see also Bd. of Ed. ex rel. Bd. of Trustees of Florida State Univ. v. Am.

Bioscience, 333 F.3d 1330, 1342 (Fed. Cir. 2003) (although

inventor had allegedly used putative co-inventor's "secret" method of making certain compounds, co-inventor "neither made the claimed compounds nor attempted to make them, and he did not have a firm and definite idea of the claimed combination as a whole"). In short, "Kimberly-Clark does not stand for the proposition that building upon a relevant report on its own rises to the level of collaboration, because as the Federal Circuit stated, joint behavior is required." Rubin v. Gen. Hosp. Corp., No. 09-10040, 2011 WL 1625024, at *7 (D. Mass. Apr. 28, 2011) (denying joint inventorship claim even where putative joint inventors sent article abstract to named inventor, who "reviewed it and used it to build upon his own research") (internal quotation omitted); cf. IP Innovation L.L.C. v. Red Hat, Inc., 705 F. Supp. 2d 692, 694 (E.D. Tex. 2010) (denying summary judgment on an invalidity challenge based on misjoinder of three named inventors, working at the same company, where deposition testimony did not conclusively show that invention was the result of "completely separate development efforts").

UUtah next argues that Bass is a co-inventor because Tuschl appropriated the draft minireview hypothesis in the twenty-eight days before it was published in *Cell*, while it was still a confidential manuscript. It relies on the Federal Circuit's decision in <u>Univ. of Colorado Found. v. American Cyanamid</u>, 342 F.3d 1298, 1302-03 (Fed. Cir. 2003), a case with a complicated

history, to support its argument that joint inventorship may stem from a named inventor reading a confidential manuscript and poaching it as his own. The American Cyanamid plaintiffs submitted an article to the New England Journal of Medicine. Afterward, in July 1981, the plaintiffs sent a confidential manuscript of that article to the defendant, with whom they had a "longstanding personal and professional relationship." Id. at 1308. The Journal rejected the article, which was published in another magazine about two years later. In the interim, in August 1981, the defendant copied and pasted portions of that manuscript and began to seek patent protection as the sole inventor without adding any of his own work or acknowledging the plaintiffs' contribution. The court concluded that the plaintiffs were the inventors and that the named inventor "had no role in conceiving the invention." Id. at 1304. Accordingly, the court upheld a finding of unjust enrichment because it was "a proper legal claim to remedy the breach of contract implied in law for disclosure of the confidential transcript in exchange for a promise not to disseminate the idea without the [plaintiff's] comment." Id. at 1306. The court emphasized that the plaintiffs were not seeking "to prevent the use of information placed in the public domain." Id. at 307 (emphasis in original). American Cyanamid is distinguishable because the manuscript there had not entered the public domain when the

defendant passed it off as his own. Even if Tuschl did begin to incorporate Bass's hypothesis into his research prior to the minireview's publication, he would have received the same information as prior art three weeks later.

On a related note, there is much debate over UUtah's argument that the minireview was confidential before its publication, and that Tuschl breached this confidentiality by beginning to incorporate Bass's Dicer hypothesis into his conceptualization of the invention during this period. 4 This theory ultimately affords UUtah little traction. UUtah first cites Cell magazine's 2015 Reviewer Confidentiality Policy. But there is no evidence to show that this policy was in place fifteen years ago when Tuschl read the preprint, much less that Tuschl was actually a peer reviewer like Zamore. Indeed, the record suggests that Tuschl received the preprint as a courtesy from Cell because Bass had reviewed his article. UUtah next argues that an implied confidentiality policy governed the distribution of the preprint. Even if this is so, and even if Tuschl breached that policy by drawing a siRNA molecule with a 3' overhang in Dr. Lendeckel's notebook before the minireview was published, that is not evidence of collaboration between

⁴Defendants contend that Tuschl made little, if any, use of Bass's Dicer hypothesis before the minireview was published. I draw all reasonable inferences in Bass's favor on this point.

Tuschl and Bass. UUtah cites no case law suggesting that a breach of a confidentiality agreement, without more, suffices to support claims for joint inventorship. While in some circumstances, an unjust enrichment claim may spring from a "wrongful use" of a confidential manuscript, see American Cyanamid, 342 F.3d at 1306, there is no evidence here that any wrongful use of the Dicer thesis during the three-week prepublication hiatus harmed Bass.

To support its claim of collaboration, UUtah points also to (1) the slide show presentation Bass gave at the Banbury Conference, and (2) the conversation Bass had with Tuschl at the Uppsala Conference. As to Banbury, the parties agree that the substance of Bass's April 11, 2000 slide show presentation was functionally identical to the contents of her minireview. This evidence thus has limited utility because Tuschl had received the minireview six days before the Banbury conference. As such, Tuschl had already seen the hypothesis in the minireview, and would soon see it again once published in Cell.

Just one piece of evidence gives me pause: the conversation between Bass and Tuschl in Uppsala, Sweden. This is the only evidence of an open line of conversation between Tuschl and Bass regarding RNAi. UUtah relies on this conversation, which occurred over dinner at the Uppsala conference in August 2000, several months after the minireview was published. Bass

remembered telling Tuschl that she had used dsRNA in the nematode worm *C. elegans* to "knock down RNAi components," meaning to prevent certain mRNA from synthesizing proteins. Bass Depo. at 126:14-15. They also discussed problems involving "northern blots." Tuschl later emailed Zamore a "word of caution with northern blots of 21mers" based on his conversation with Bass. Boebel Decl., Ex. 9. Based on Bass's recollection⁵ and Tuschl's email, UUtah insists that the Uppsala conversation supports its claim of joint inventorship.

To begin with, the parties did a poor job in explaining the scientific significance of Bass's work with the *C. elegans* worm⁶ or her references to northern blots. A review of the record reveals that neither topic bears directly on the subject matter of the Tuschl II patents. First, Bass remembered very little about the discussion of her experiments with the *C. elegans* worm, whose frequent use in the RNAi field is well-established.⁷ Bass conceded there was nothing in those conversations that were "questioned in the patents . . . [because] 3' overhangs were accepted by that time." Second, the "northern blot" test

⁵ Tuschl did not remember speaking to Bass at Uppsala.

⁶ According to UUtah's expert, Dr. Richard Jorgensen, studies of RNAi in the *C. elegans* worm existed in the mid 1990's. <u>See also</u> https://en.wikipedia.org/wiki/Caenorhabditis_elegans (describing *C. elegans* worm) (last accessed September 14, 2015).

 $^{^{7}}$ See Jorgensen Report at ¶¶ 39, 40, 45.

referenced in Tuschl's email is a common lab technique that has been used for decades. These tests, which are not unique to the RNAi field, use a nucleic acid probe to detect and quantify radioactive RNA molecules that have been placed on a blotting membrane. So while Tuschl and Bass may have been discussing northern blot tests and the nematode worm C. elegans in relation to RNAi research, their dinner conversation does not constitute clear and convincing evidence that Bass's comments with respect to northern blot protocol and C. elegans were significant contributions to the Tuschl II patent inventions.

In any event, sharing information at scientific conferences, without more, does not constitute joint inventorship. After all, that is the point of scientific discourse, and any contrary ruling would not only contravene the statute and case law but would also impede innovative research.

As the Supreme Court recently acknowledged,

patent protection strikes a delicate balance between creating incentives that lead to creation, invention, and discovery and impeding the flow of information that might permit, indeed spur, invention.

Myriad, 133 S.Ct. at 2116. Here, there is no clear and convincing evidence that the dinner meeting between these two brilliant scientists constituted collaboration in support of

⁸ See Docket No. 189, Ex. 38, Jorgensen Depo. at 85:2-19; 87:8-25; see also https://en.wikipedia.org/wiki/Northern_blot (last accessed September 10, 2015).

joint inventorship. Compare Falana, 669 F.3d at 1352, 53-54 (joint inventorship where plaintiff had worked with named inventors for years and those inventors described research as "very much a team process"); Ethicon, 135 F.3d at 1462-64 (joint inventorship where parties collaborated for eighteen months to develop surgical tool and putative inventor contributed crucial elements of device); and PerSeptive Biosystems, Inc. v.

Pharmacia Biotech, Inc., 12 F. Supp. 2d 69, 85 (D. Mass. 1998) (joint inventorship where inventors researched proteinseparating particle together, shared laboratory data, and exchanged ideas relating to patent), with Eli Lilly, 376 F.3d at 1363 (putative co-inventor could not show joint inventorship where he remembered no conversations about invention itself during meeting with named inventors).

ORDER

The defendants' motion for summary judgment as to correction of inventorship (Docket No. 165) is <u>ALLOWED</u>. The defendants' motion for summary judgment as to UUtah's state law claims (Docket No. 168) is <u>ALLOWED</u>. The defendants' motion to strike the expert report of Dr. Putnam (Docket No. 205) and UUtah's partial motion to strike the expert report of Dr. Kunin (Docket No. 209) are <u>DENIED</u> as moot.

/s/ PATTI B. SARIS
Patti B. Saris
Chief United States District Judge